

BRIEF IN SUPPORT OF PETITION.

Preliminary Matters.

Opinion Below.

The opinion of the United States Court of Appeals for the District of Columbia may be found in the record at page 273. It is reported in 140 Fed. (2d) 18.

Jurisdiction.

The decree of the United States Court of Appeals for the District of Columbia now sought to be reviewed was entered on February 5, 1944.

The jurisdiction of the Court is based upon Section 5 (c) of the Act of March 21, 1938 (52 Stat. 111, Title 15 U. S. C. A. Section 45), and Section 240 of the Judicial Code, Act of March 3, 1911, Chapter 231, 36 Stat. 1157, as amended by Section 2 of the Act of February 13, 1925, Chapter 229, 43 Stat. 936.

Statement of Case.

The principal facts have been summarized in the petition, *supra*, pages 1 and 2.

Statute Involved.

Section 5 of the Act of March 21, 1938 (52 Stat. 111, Title 15 U. S. C. A. 45).

Specification of Error.

The Court below erred in affirming the order of the Federal Trade Commission and holding that there was evidence to support it.

Argument.

As will be seen from the findings of the Federal Trade Commission and the Order (Record 10-22) in this case the Commission was not content with prohibiting the respondent from making the representations which it determined to be false and misleading, but went further by requiring the respondent to make no representations whatever to the effect that the preparations sold by it have any therapeutic value whatsoever in the treatment of any form of sterility (Order 1b, Record 20), or have any value in promoting or aiding the functioning of the female reproductive organs (Order 1c, Record 20). This means that these preparations cannot under the order of the Commission, as sustained by the Court of Appeals, be offered for sale under the representations complained of or under any other representations in any way claiming them to have any merit in any form of sterility. It was argued before the lower court that in such prohibition the Commission went too far and that these provisions of the order were neither justified by the evidence nor supported by the findings of the Commission. The Court nevertheless held in its opinion that the "findings are amply supported by the evidence."

All of the testimony adduced in this case on the question of the value of these preparations was that of medical men, and was all opinion testimony. The question in the case is not whether there was a difference of opinion between the witnesses who testified, as clearly was the case, or whether the Commission could properly resolve such dif-

ference of opinion, but whether the testimony of all the witnesses did not conclusively show as a fact that the merit of the ingredients for use in functional sterility was a matter of opinion generally and one that had not been resolved by the medical profession itself. If so, then it is respectfully contended that the Commission was without authority to resolve this matter of opinion itself, and could properly go no farther than to hold that under present medical knowledge the value of the treatment in functional sterility was an undetermined and undeterminable question. Conceding *arguendo* that it could lawfully require the respondent to discontinue representations which it found to be misleading, it is respectfully submitted that in going farther and precluding the respondent from expressing its opinion in any terms upon an undetermined and undeterminable matter, it acted without authority of law.

As stated in the Commission's findings (paragraph 3, Record 13): "It is the respondent's contention that the general health of a woman has a direct bearing upon sterility and that the administration of the various tonics combined in respondent's preparation tones up the general health, with a favorable reaction upon the female organs." It was the further contention of respondent that the laxative preparation is of value to this end in relieving constipation, that the douche is of value in overcoming excessive acidity and in stimulating the tissues by means of heat, and that viburnum pruniflorous, Vitamin E, and ovarian substance have a direct value in toning up the female organs. The Commission in its findings admits that ferrous sulphate "is an iron preparation effective in cases of anemia," that gentian was formerly used as a stomachic and has perhaps some tonic value and that nux vomica is a substance from which strychnine is obtained, which has a stimulating effect upon gastric secretions and is a nerve

stimulant which tends to relax the nerve endings (Findings, paragraph four, Record 14), and nowhere denies that these ingredients would tend to build up anemic and asthenic women, as contended by respondent. Indeed, a reading of the findings as a whole warrants the assumption that it is not this claim to which the Commission takes exception, but to the further contention that by the building up a woman in poor health the chances of conception are increased. The Commission says that the toning up of the system will not, in itself, overcome sterility (Findings, paragraph five, Record 16). Whether, in the opinion of the Commission, it would help in any case, is not stated. The Commission holds, however, in paragraph 5 of the findings (Record 17), that the treatment as a whole possesses no beneficial properties which have any value in promoting or aiding the function of the female reproductive organs.

The Commission in its findings further admits, it may be noted, that the laxative tablets have value in the temporary relief of constipation; that viburnum pruniflorous is a drug which was formerly used as a uterine tonic or sedative, although now thought to be relatively inert, and that the value of Vitamin E, "sometimes referred to as a sterility vitamin," *has not been definitely determined*. It holds definitely that ovarian substance is considered to be inert and of no value when administered orally. The douche the Commission finds might have a tendency to temporarily neutralize the acid condition of the vagina, but asserts that this would be of no value in favorably affecting sterility.

Particular reference is made to the Commission's findings with reference to Vitamin E to the effect that its value has not been definitely determined; yet in its order we find the Commission definitely barring the respondent from expressing the opinion that it has value in functional sterility

and impliedly resolving a medical question which in its findings it concedes even the medical profession has not settled.

A findings of fact upon which to predicate an order of the Commission is a necessity. *Arnold Stone, Inc. v. Federal Trade Commission*, 49 Fed. (2d) 1017.

With reference to this ingredient, Vitamin E, the testimony of the physicians who were called by the Commission, considered alone, reveal that the findings of the Commission that its value has not been definitely determined is well supported therein.

Dr. Losli testified to the effect that in view of the work that has been performed by reputable men he would not cast any aspersions on calling it the anti-sterility vitamin (Record 29). Dr. Marley had no personal knowledge of it, but stated that it is mostly prescribed to increase fertility (Record 36). Dr. Kelly, a witness for the Commission, testified that it had been shown it was necessary for fertility in laboratory animals but that it was a medical question still to be settled as to whether it was necessary in humans (Record 40). Similar testimony was given by Dr. Neustaedter (Record 42, 43). Dr. Kurzrok stated that there was no question about it being a factor in the sterility of rats, but that *there was a conflict of medical opinion as to its usefulness in human sterility* (Record 44). Dr. Schomer was of the same opinion (Record 46). He also stated it had empirical value but that it was in the clinically experimental stage at the present time (Record 47).

If there were nothing more to be considered in petitioner's preparations than Vitamin E, the testimony in regard thereto and the findings of the Commission *supra* should have precluded the holding of the Commission that there is nothing in petitioner's preparations, singly or in combina-

tion, that would affect fertility or influence the reproductive organs.

Somewhat the same situation exists with reference to the so-called tonic ingredients contained in this product. The findings of the Commission that the toning up of the system will not, in itself, overcome sterility, does not constitute a holding that it might not be a factor in the attaining of such an end, and the testimony of physicians called for the Commission concedes that there are some cases in which improvement in health would relieve functional sterility, and indicates that this is a question on which there is no uniform medical opinion. For instance, Dr. Losli, a witness for the Commission, stated that functional sterility is caused by poor health (Record 28); that it could not be definitely stated what aid the treatment might be in cases of functional sterility (Record 28), and that there might be one in a hundred women suffering from functional sterility who might need iron (Record 34). Commission's witness Dr. Marley indicated that it is not generally true that the overcoming of a run-down condition would enable a woman suffering from functional sterility to conceive, but that there are cases otherwise (Record 36). In answer to the direct question whether functional sterility is frequently ascribed to poor health and low vitality and not organic disease, he answered "Yes and no" and declined to elaborate on that answer (Record 35). Dr. Neustaedter, another of the Commission's witnesses, testified that whether the building up of a woman in poor physical condition would make her more likely to conceive is dependent on the fact of whether or not the pelvic organs are perfectly normal; that the building up of a woman by the use of tonics would have neither a direct nor indirect effect upon the reproductive organs but would help if the metabolism of the body economy is affecting the possible pregnancy (Record

42-43). Commission's witness Dr. Kurzrok testified that asthenia and functional sterility might occur at the same time and that in overcoming asthenia the functional sterility might be overcome at the same time because basically they might be the same condition (Record 45). In a qualified way, Dr. Schomer, another witness for the Commission, agreed with Dr. Kurzrok, stating in substance that, although the proportion of cases is so very light, nevertheless in some cases functional sterility might be ascribed to asthenia and if the asthenia were resolved it might resolve the sterility (Record 48).

There is not a great deal of testimony in the record regarding the remaining few ingredients, ovarian substance, viburnum pruniflorous and alkaline douche, but there is some tending to bring them within the same rule. However, it is respectfully contended that the findings and testimony are such with reference to Vitamin E, iron, gentian and nux vomica (strychnine) as to show beyond question that the Commission was without jurisdiction in issuing so drastic an order, and that the Court of Appeals was in error in holding the evidence sufficient to support the Commission's order.

Petitioner feels strongly that the facts in this case fall directly within the rule enunciated by this Honorable Court in *American School of Magnetic Healing vs. McAnnulty*, 187 U. S. 94, a case that has frequently been cited as support for the contention that an administrative tribunal is without authority to determine one way or another questions which are in the realm of conjecture and opinion and not susceptible of being definitely answered. This opinion, while it has frequently been distinguished, as in *Leach v. Carlisle*, 258 U. S. 138, has never been overruled. It was followed in *Post v. U. S.*, 135 Fed. 1, and cited with ap-

proval in *L. B. Silver Co. v. Federal Trade Commission*, 289 Fed. 985, and many other cases. As this Honorable Court knows, the opinion in the *McAnnulty Case* was rendered in a situation where the Postmaster General had issued a so-called "fraud order" against the American School of Magnetic Healing, which claimed mental treatment to be a valuable therapeutic agent. In the course of his opinion, Justice Peckham said:

"The opinion entertained cannot, like allegations of fact, be proved to be false; and therefore it cannot be proved, as a matter of fact, that those who maintain them obtain their money by false pretenses," and further:

"As the effectiveness of almost any particular method of treatment is, to a more or less extent, a fruitful source of difference of opinion, even though the majority may be of one way of thinking, the efficacy of any special method is certainly not a matter for the decision of the Postmaster General, within these statutes relative to fraud."

It may well be argued *contra* that there have been many cases decided by the Post Office Department and by the Federal Trade Commission since the decision in the *McAnnulty case* involving representations regarding drugs and that such decisions have frequently been upheld by the Courts. But it is respectfully submitted that such cases only involved a difference of opinion between witnesses who testified and not such testimony as appears in the instant case, showing beyond doubt that the efficacy of the medicines sold has not been decided and cannot be decided as a fact at the present time by those on whose opinions the Commission must rely, that is, the medical profession itself. Here is not solely a difference of opinion between experts on each side, but a showing by testimony of both sides that the question in issue is still unsettled and unresolved.

This has frequently been the case in medicine with reference to agents concerning which research and experiments was still going on. What would the Commission have said a decade or so ago about expressions of opinion regarding vitamins to the effect that they would accomplish the things it has now been proved they can accomplish, such as the cure of pellagra and beri-beri? Some men were then convinced of the real value of these factors, but it was only a matter of opinion, not yet fully confirmed by experiment. The same question could also be asked about the "sulfa" drugs, about penicillin and about many other drugs.

It may well happen that further research and experiment by the medical profession will fully confirm the opinions expressed by the petitioner, or otherwise, but until that time comes, it is respectfully submitted that the Commission may not lawfully decide the question itself, and issue such an order as it has herein enjoining the petitioner from claiming its preparations have any therapeutic value in the treatment of any form of sterility, or in promoting or aiding the function of the female reproductive organs.

Opinions cannot be accepted as evidence of a fact unless based upon expert testimony on known scientific facts. *Elliott Works v. Frisk*, 58 Fed. (2d) 820. Where it appears that an expert's opinion is pure speculation, such opinion will not be regarded as substantial evidence. *Svenson v. Mutual Life Insurance Co.*, 87 Fed. (2d) 441.

It is a well established rule of law that all quasi-judicial orders of a plenary nature issued by an administrative agency, to be valid must be supported by substantial, credible evidence, and that such evidence, as was said by the Supreme Court in *Del Vecchio v. Bowers*, 296 U. S. 280, 285, must be such as to induce conviction. It is also well established that administrative boards and agencies must de-

cide cases on *all* the evidence and their findings and order must be based upon substantial, credible evidence. *Peninsular and Occidental Steamship Co. v. National Labor Relations Board*, 98 Fed. (2d) 411, 412.

“Substantial evidence” means more than a mere scintilla. It is of substantial and relevant consequence and excludes vague, uncertain or irrelevant matter. It implies a quality of proof which induces conviction and makes an impression on reason. It means that the one weighing the evidence takes into consideration all the facts presented to him and all reasonable inferences, deductions and conclusions drawn therefrom, and considering them in their entirety and relation to each other, arrives at a *fixed conviction*. *National Labor Relations Board v. Thompson Products, Inc.*, 97 Fed. (2d) 13, 15; *National Labor Relations Board v. Louisville Refining Co.*, 102 Fed. (2d) 678 (Cert. denied, 308 U. S. 568); *National Labor Relations Board v. Columbia Enameling and Stamping Co.*, 306 U. S. 292; *Consolidated Edison Co. of N. Y. v. National Labor Relations Board*, 305 U. S. 197, 229, 230. See also *Pennsylvania R. R. v. Chamberlain*, 288 U. S. 333, 343, and cases cited therein.

In administrative proceedings it is incumbent upon the agency to prove its charges and the evidence must be competent and substantial. *Philip Carey Mfg. Co., et al. v. Federal Trade Commission*, 29 Fed. (2d), 49; *Morgan v. United States*, 304 U. S. 1.

It is respectfully submitted that the opinion of the United States Court of Appeals for the District of Columbia sustaining so much of the order of the Federal Trade Commission as requires respondent to refrain from claiming its preparations to be of any therapeutic value in any form of sterility or beneficial to the functioning of the female reproductive organs was in error in holding there was ample

evidence to support such prohibition, that the evidence relied upon was neither ample, sufficient nor substantial, that such prohibition was not supported by the findings of the Commission and that the Court should have ordered such prohibition stricken from the order.

Conclusion.

It is respectfully submitted that this case involves matters which should be reviewed by this Court and that a Writ of Certiorari should be issued for that purpose.

HORACE J. DONNELLY, JR.,
Counsel for Petitioner.

Due service of the within petition and brief is hereby acknowledged this day of , A. D., 1944.

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Counsel for Respondent.

